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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,998

08/18/2003

John D. Hatlestad

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EXAMINER

MUSSELMAN, TIMOTHY A

ART UNIT

PAPER NUMBER

3715

MAIL DATE

DELIVERY MODE

12/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/642,998	<b>Applicant(s)</b> HATLESTAD ET AL.	
	<b>Examiner</b> TIMOTHY MUSSELMAN	<b>Art Unit</b> 3715	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-12, 14, 35-39, 42-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 6, 40 and 41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

***DETAILED ACTION***

***Status of Claims***

Applicant's submission dated 8/13/2009 has been received, and claims 1-12, 14, and 35-46 are pending. Claims 13, 15-34, and 47-96 have been cancelled previously.

***Claim Rejections - 35 USC § 103***

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

**Claims 1-5, 7-12, 14, 35-39, and 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (US 5,520,176) in combination with Bardy (US 6,398,728) and 'Aircraft Noise and Sleep Disturbance: Final Report', prepared by the Civil Aviation Authority London on behalf of the Department of Trade, August 1980.**

**Regarding claims 1, 14, 35-36, and 46,** Cohen discloses a system and methods for sleep quality data collection and analysis utilizing various measured physiological parameters. See col. 2: 33-59. Cohen fails to teach of utilizing non-physiological parameters in the research process. However, a *research* study conducted by the Civil Aviation Authority London published in 1980 pertains explicitly to this very subject. See page two, in the report summary, wherein it is described how aircraft noise was *measured* in

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various London neighborhoods on aircraft approach paths to the two main London airports in order to better understand how the noise interfered with the *sleep processes* of residents. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate background noise measurements (i.e. non-physiological parameter measurements) in the manner of the 1980 CAA *sleep quality research* project, into the *sleep research* System of Cohen, in order to expand the usefulness of the research system of Cohen to include cause and effect data pertaining to sleep problems.

Cohen additionally fails to teach wherein the collection and storing of sleep quality data occurs on the implantable device, and wherein the implantable device performs the evaluation, and also wherein the non-physiological data is collected external to the patient and transmitted to the implantable device (claims 36 and 46). However, Bardy discloses an implantable device utilized for research purposes that measures various parameters with various sensors. See col. 8: 1-17. This citation describes an implantable analysis system, wherein the data can be collected, stored, and processed internally, externally, or transmitted between internal and external system components. Bardy also discloses wherein it is known to include location information in studies. See col. 7: 25-35. It would have been obvious to one of ordinary skill in the art at the time of the invention to include such a distributed sensory and processing system, and particularly to have the processing occur internally to the patient, to improve the product in a manner as taught by Bardy, by allowing the device to process data and thus reducing the need for frequent external data analysis by a human (i.e. the device would transmit a derived measure, rather than simply raw data).

**Regarding Claims 2-4, 8-12, 37-39, and 43-45** Cohen further discloses the detection and determination of metrics pertaining to; sleep quality (**Claims 2 and 39**), see col. 6: 12-20; respiratory and disordered breathing conditions (**claims 3, 11, 43, and 45**), see col. 4: 3-10 and col. 4: 41-45; muscle system and movement disorder conditions (**claims 4, 12, and 44**), see col. 8: 38-45; blood chemistry conditions (**claim 5**), see col. 5: 33-35; contextual conditions (**claim 8**), see the provided citations for claims 2-6; and data pertaining to sleep stages and sleep disruptions (**claims 9-10 and 37-38**), See col. 7: 20-25.

**Regarding claims 5 and 42**, Cohen further discloses wherein the metrics are trended over time. See col. 3: 17-37.

**Regarding claim 7**, the detection of environmental conditions (e.g. background noise) for sleep research is an obvious variation of Cohen in view of the CAA report as described above with regard to claim 1.

### ***Allowable Subject Matter***

**Claims 6 and 40-41** are objected to as being dependant from a rejected base claim, but would be allowable if rewritten to include all of the features of the base claim and any intervening claims. These claims are considered allowable because the prior art does not teach or suggest a system for analyzing sensed physiological and non-physiological data pertaining to a sleep quality analysis, wherein the data is analyzed on the implantable device, and wherein the non-physiological data includes air quality data and ambient temperature data.

### ***Response to Arguments***

Applicant's remarks dated 8/13/2009 have been fully considered, but no arguments were presented to accompany the claim amendments.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action

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is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY MUSSELMAN whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571)272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. M./  
Examiner of Art Unit 3715

/XUAN M. THAI/  
Supervisory Patent Examiner, Art Unit 3715